1. **Policy Statement**

   This policy provides guidance to employees of the schools, departments and units that are a part of Rutgers Biomedical and Health Sciences and other Rutgers University schools, units and departments that bill federal or state programs for healthcare-related goods or services (“Related Healthcare Entity” or “Related Healthcare Entities”) as to how to execute certain types of agreements with Referral Sources.

2. **Reason for Policy**

   To provide guidance as to how the Related Healthcare Entities policy may enter into financial arrangements with physicians and other Potential Referral Sources, as defined below, and to ensure compliance with Stark Law, the federal Anti-kickback statute and with the regulations, directives and guidance related to those statutes.

3. **Who Should Read This Policy**

   This policy applies to and should be read by employees of the schools, departments and units that are a part all Rutgers Biomedical and Health Sciences and other University schools, units and departments that bill federal or state programs for healthcare-related goods or services (“Related Healthcare Entity” or “Related Healthcare Entities”), including but not limited to hospitals, physician practices, and outpatient centers. The policy should also be read by departments that support the Related Healthcare Entities, including but not limited to Finance, the Office of the Senior Vice President and General Counsel and University Procurement Services. The policy applies to any agreement or financial relationship involving, i) a physician or, as set forth below, a non-physician referral source, or ii) a physician’s immediate family members (herein and in this policy, all may be referred to as “Referral Sources”).

All regulations and procedures are subject to amendment.
4. Related Documents

A. 42 U.S.C. § 1320a-7b; 42 C.F.R. § 1001.952(a)-(v); 42 U.S.C. § 1395nn; 42 C. F. R. § 411.350 et. seq.;
C. 66 Fed. Reg. 856 (Jan. 4 2001); 69 Fed. Reg. 16054 (March 26, 2004);
E. Policy 100.2.4 Professional Services Agreement
F. Policy 100.2.7 Focus Arrangement Database
G. Policy 100.2.1 General Statement on Agreements with Referral Sources
H. Policy 100.2.3 Fair Market Valuation
I. Policy 20.1.11 Purchasing Policy
J. Policy 20.1.16 Policy on Notification and Approval of Certain Contracts Awarded without Competitive Bids or Proposal
K. Policy 20.1.17 Engagement and Payment of Professional Service Provider Policy
L. Policy 40.2.12 Gratuities, Guests, Gifts and Use Of University Resources
M. Policy 40.2.5 Consulting or Other Personal Services, Intellectual Property, Honoraria and Other Miscellaneous Activities Policies and Procedures for Payment
N. Policy 50.3.13 Signatory Authority

5. Contacts

Chief Healthcare Compliance Officer 973-972-8093
Office of the Senior Vice President and General Counsel 848-932-7697
University Finance

6. The Policy

100.2.1 GENERAL STATEMENT ON AGREEMENTS WITH REFERRAL SOURCES

The Related Healthcare Entities will, from time to time, promulgate various policies as to financial relationships between the Related Healthcare Entity Operating Units and (i) physicians and (ii) other Potential Referral Sources. Compliance with the policies is required in all contracts with physicians and other referral sources.

Definition of Actual Referral Source
An actual source of healthcare business or referrals to a Related Healthcare Entity, or between a Related Healthcare Entity and a physician (or a physician's immediate family member as defined at 42CFR Sec.411.351) --include, but are not limited to, another Physician, hospitals, long-term acute care centers, nursing homes, clinics, physician group practices, therapists and other individuals and entities who are in a position to influence or make referrals.

Definition of Potential Referral Source
A potential source of healthcare business or referrals to a Related Healthcare Entity or between a Related Healthcare Entity and a physician (or a physician's immediate family member as defined at 42CFR Sec.411.351) --include, but are not limited to, another Physician, hospitals, long-term acute care centers, nursing homes, clinics, physician group practices, therapists and other individuals and entities who are in a position to influence or make referrals.

Requirements:

A. In general, in compliance with 42 U.S.C. § 1395nn, commonly known as “the Stark Law,” and 42 U.S.C. §1320(a)-7b(b), commonly known as the Anti-kickback Statute, and with statutory exceptions and safe harbors, an agreement with a Referral Source must:
   i. be in writing, signed by the parties and must specify the services covered;
ii. specify the timeframe for the arrangement, the term of which must not be for less than one year;

iii. specify the consideration (i.e., rent, purchase price, compensation) and set the consideration in advance (with the exception of employment agreements), consistent with fair market value (refer to policy on Fair Market Valuations) for services or items actually provided without taking into account the value or volume of referrals or other business generated by the Referral Source; and

iv. be intended to obtain or provide an item or service that is reasonable and necessary for a legitimate business purpose.

Depending on the nature of the Subject Agreement (i.e., lease of space, professional services agreement, affiliation agreement), additional regulatory requirements may apply in order to fulfill the provisions of applicable legal exceptions or safe harbors. To the extent the Subject Agreement is a Focus Arrangement, as such is defined under the Corporate Integrity Agreement between UMDNJ and the Department of Health and Human Services Office of Inspector General, dated September 25, 2009 as amended by a Letter Agreement, UMDNJ-Rutgers University dated 5/1/2013, the Focus Arrangements Database policy and Focus Arrangements Approval Procedure apply and must be followed.

Other forms of agreements, such as "letters of intent," "letter agreements," or "memoranda of understanding" are subject to this policy. Individuals working within the Related Healthcare Entities, including, but not limited to, its clinical units and departments, must not enter into side agreements or arrangements whether written or oral with physicians or facilities without the explicit approval of the department chair and dean or chief executive officer. This policy also applies to all amendments and extensions/renewals of Subject Agreements with physicians or facilities. If at any time it appears that there have been discussions or memoranda indicating intent to induce referrals by way of a Subject Agreement, such Subject Agreement will not be approved.

All Subject Agreements with potential referral sources must be reviewed and approved by the responsible department head, dean, chief executive officers and the Office of Senior Vice President and General Counsel prior to execution. In most cases, this approval is evidenced by signatures on the applicable term sheet or approval form. Legal review and approvals must be obtained even if the Subject Agreement complies in all respects with Rutgers and RBHS policies. Legal review and approvals also must be obtained for amendments to existing Subject Agreements that revise the payment terms or the effective dates of the existing Subject Agreement. It is not acceptable to obtain the appropriate approvals after making payments in accordance with the Subject Agreement. Commitments to physicians may not be made until written approvals have been obtained from the responsible dean, chief executive officer and the Office of the Senior Vice President and General Counsel. Signatory authority for all Subject Agreements is subject to the Rutgers Signatory Authority policy.

B. The RBHS Office of Ethics, Compliance and Corporate Integrity will educate responsible parties on the laws, regulations and policies applicable to Subject Agreements with Potential Referral Sources, will monitor and review such Subject Agreements, will ensure that fair market value documentation attached to Subject Agreements reflects fair market value for the services rendered and will assist the responsible dean or chief executive officer with remediating such Subject Agreements when potential violations of this policy are detected.

C. Execution Timing: The Subject Agreement must be fully executed before any services are provided and before payment is made or received.
D. Compliance with Subject Agreement terms: In all arrangements with Potential Referral Sources, payments must be consistent with the terms of the Subject Agreement and performance of all of the terms of the Subject Agreement is required. For example, monies owed by a physician under a lease agreement must be paid in accordance with the terms of the documents. Accurate and complete records of all time and effort must be maintained by the facility, clinical unit or department. The Related Healthcare Entity must accurately track remuneration paid or received pursuant to an agreement. The RBHS Office of Ethics, Compliance and Corporate Integrity is responsible for conducting annual probe sample reviews for time and effort reporting and remuneration tracking.